REMARKS / ARGUMENTS

1. Response to 12/12/2007 Office Action

For the convenience of the Examiner and clarity of purpose, Assignee has reprinted the substance of the Office Action in ***10-point bolded and italicized font.*** Assignee's arguments immediately follow in regular font.

> ***Applicant's arguments filed 10/15/07 have been fully considered but they are not persuasive. The argument that the "diastolic VAD flow rate is considered herein as the VAD flow contribution below the mean VAD flow rate" and that Nagyszalancyzy does not teach monitoring or receiving the diastolic flow rate as a function of the mean flow rate is not persuasive for three reasons. First, the mean flow rate is not used as a claim limitation. Second, unless the specification specifically and clearly sets forth that a special definition for a term is to be applied to the claims, that term is to be given its broadest reasonable interpretation. Since the specification does not specifically and clearly set forth a special definition for "diastolic VAD flow rate" the term has been given its broadest reasonable interpretation. It is suggested to specifically claim how the diastolic VAD flow rate is measured in comparison to the mean flow rate. Finally, since Nagyszalancyzy continuously monitors the flow rate during systole and diastole to continuously change the speed of the pump he will/does measure the VAD flow contribution below the mean VAD flow rate and change the speed based on the diastolic VAD flow rate.***

Assignee has retracted the previous amendments to the claims. Therefore, in light of the mootness of the above rejections and Response to Arguments, Assignee hereby expressly retracts its previous arguments with respect to previously presented claims 1 - 20 in accordance with *Hakim v. Canon Avent Group PLC*, 479 F.3d 313, 81 U.S.P.Q.2d (BNA) 1900 (Fed. Cir. 2007).

> ***Claims 1, 3, 5, 7, 8, 10, 11, 14, 15, 19, and 20 are rejected under 35 U.S.C. 102(b) as being anticipated by Nagyszalancyzy et al (6048363). Nagyszalancyzy discloses a blood pump that continuously monitors during systole and diastole the flow rate and increases or descreases the pump speed based on the flow rate to achieve the proper pump operating point (e.g. columns 14-16, table 1, figures 22 and 23, etc.) and therefore will monitor diastolic pump flow and change the speed in response to the flow. For claims 14, 15, 19, and 20, Nagyszalancyzy describes (e.g. columns 13-15) the use of setting the predetermined speed in accordance with activities such as sleeping and the implantable pressure sensor.***

Claim 1 recites "changing the predetermined speed in response to the diastolic pump flow rate" and has been amended to explicitly require that "the diastolic pump flow rate is a flow contribution below a mean flow rate". Claim 7 recites "***extract*** a diastolic pump flow rate from the blood flow rate signal" and "vary the speed of the pump in response to the diastolic pump flow rate", emphasis added. Claim 7 has also been amended to explicitly require that the "diastolic pump flow rate is a flow contribution below a mean flow rate".

Support for these amendments may be found, among other places, in paragraphs 29-31, reproduced below, emphasis added:

> [0029] The contraction phase of the heart beat is referred to as systole, the relaxation phase is referred to as diastole. Thus, the systolic VAD flow is the maximum VAD flow rate, while the diastolic VAD flow rate is the minimum VAD flow rate. It has been determined (empirically) that a patient's diastolic VAD flow rate significantly increases at the onset of exercise, and decreases at the conclusion of exercise. In comparison, the systolic VAD flow rate, for example, remains relatively constant at the onset and conclusion of exercise. Thus, in certain embodiments of the invention, the pump speed is adjusted in response to changes in the diastolic VAD flow rate.
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> [0030] The contraction phase or pumping phase of the cardiac cycle is referred to as systole, the relaxation phase or filling phase is referred to as diastole. In healthy, non-VAD patients, there is positive blood flow, from the left ventricle through the aortic valve, during systole and no blood flow, from the left ventricle through the aortic valve, during diastole. However, in patients who have been implanted with a left VAD there is generally positive flow through the VAD during both systole and diastole. This is because the implanted continuous flow VAD essentially adds a constant positive flow offset to the native heart's pulsatile flow contribution.
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> [0031] Therefore, the conventional definitions for systolic flow and diastolic flow must be modified to make them applicable to patients implanted with left VADs. ***Thus, the systolic flow rate is considered herein as the flow contribution above the mean flow rate value, while the diastolic VAD flow rate is considered herein as the VAD flow contribution below the mean VAD flow rate.*** Peak systolic

> VAD flow rate is considered herein to be the maximum VAD flow rate value in the VAD flow rate waveform in one cardiac cycle and average peak systolic VAD flow rate is the average value of multiple peak systolic VAD flow rate values over several cardiac cycles. Similarly, peak diastolic VAD flow rate is considered herein to be the minimum VAD flow rate value in the VAD flow rate waveform in one cardiac cycle and average peak diastolic VAD flow rate is the average value of multiple peak diastolic VAD flow rate values over several cardiac cycles.

Thus, there is an important distinction between "mean pump flow rate" and "diastolic pump flow rate", as described in the specification and used in the claims.

In contrast, nowhere does Nagyszalancyzy discuss any flow rate below a mean flow rate. In fact, Nagyszalancyzy does not even mention the term diastolic flow. Rather, Nagyszalancyzy repeatedly refers to the flow rate as a constant volume flow rate, both implicitly and explicitly. *See, for example*, columns 7 and 8. Only in column 19, lines 8-24 does Nagyszalancyzy even acknowledge the possibility of a pulsing blood flow. Here, his "main emphasis [is] the periodic, limited change in ***pressure***", emphasis added. Column 19, lines 16 and 17. Therefore, nowhere does Nagyszalancyzy teach or fairly suggest any distinction between "mean flow rate" and "diastolic flow rate".

More specifically, nowhere does Nagyszalancyzy teach or fairly suggest "changing the predetermined speed in response to … a flow contribution below a mean flow rate", as claimed in claim 1. Furthermore, Nagyszalancyzy simply does not "***extract*** a diastolic pump flow rate from the blood flow rate signal", emphasis added, as claimed in claim 7. In fact, because Nagyszalancyzy is only concerned with a constant volume flow rate, Nagyszalancyzy actually teaches away from claim 7's recitation of "***extract*** a diastolic pump flow rate from the blood flow rate signal", emphasis added.

For at least these reasons, Assignee respectfully submits that claims 1 and 7 are patentable over the disclosure and teaching of Nagyszalancyzy. Reconsideration and withdrawal of this rejection is requested.

2. Information Disclosure Statement

An Information Disclosure Statement is filed herewith. The reference therein was cited in an Office Action from the Chinese Patent Office in a corresponding Chinese application.

3. CONCLUSION

Claims 1-15, 19, and 20 have been amended. Claims 16-18 have been withdrawn. Claims 1-15, 19, and 20 are pending in this application and Assignee submits that each claim is patentable, as detailed herein. A notice of allowance is respectfully requested.

The Commissioner is authorized to charge to deposit account 12-1322/0021906.023US any other fees necessary to make this and related papers, if any, timely and effective.

Assignee thanks the Examiner for her consideration and effort on this file. If there are any questions or if additional information is needed, the Examiner is invited to telephone or email the undersigned.

Respectfully submitted,

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